

Substitute Sheet

PCT/AT99/00154

(new) C l a i m s :

1. A preparation based on blood coagulation factor VII having a portion of less than 5% of factor VIIa, characterized by a specific amidolytic activity of at least 50 U/mg and a stability in the absence of inhibitors of blood coagulation.
2. A preparation according to claim 1, characterized by a specific amidolytic activity of at least 100 U/mg.
3. A preparation according to claim 1 or 2, with a factor VII concentration of from 50 to 5,000 U/ml.
4. A preparation according to claim 1 or 2, in lyophilized form.
5. A preparation according to any one of claims 1 to 4, which in its ready-to-use state at room temperature is stable for a period of at least 12 h.
6. A preparation according to any one of claims 1 to 5, characterized in that factor VII is an activatable, recombinant factor VII.

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7. A preparation according to any one of claims 1 to 5, characterized in that factor VII is a native, plas-matic factor VII.
8. A preparation according to any one of claims 1 to 7, obtainable by a chromatographic purification method and fractionated elution of factor VII without addition of inhibitors of blood coagulation.
9. A preparation according to any one of claims 1 to 8, characterized in that it is formulated as a pharma-ceutical infusion preparation.
10. A method for purifying factor VII from a biologi-cal materials and producing a factor VII preparation by adsorption of factor VII on a chromatographic material, fractionated elution of factor VII with a specific ami-dolytic activity of at least 50 U/mg, the elution being performed with a buffer without addition of inhibitors of blood coagulation, and recovery of factor VII from the eluate.
11. A method according to claim 10, characterized in that an anion exchanger in a column is employed as the

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chromatographic material and the flow rate of elution is at least 0.15 column volumes per minute.

12. A method according to claim 10, characterized in that a carrier with hydrophobic groups is employed as the chromatographic material.

13. A method according to claim 10, characterized in that a carrier suitable for gel filtration is employed as the chromatographic material.

14. A method according to any one of claims 10 to 13, characterized in that factor VII is purified from blood, plasma, a plasma fraction, a cell culture or a cell culture fraction.

15. A method according to any one of claims 10 to 14, characterized in that factor VII is recovered from the eluted fraction which contains factor VII with a specific activity of at least 100 U/mg.

16. A method according to any one of claims 10 to 15, characterized in that an anion exchanger is employed as the chromatographic material, and a material suitable

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for hydrophobic chromatography is employed as further chromatographic material.

17. A pharmaceutical preparation comprising a factor VII obtainable according to the method according to any one of claims 10 to 16.

18. A preparation according to claim 17, further comprising at least one of blood coagulation factors II, IX and X.

19. A preparation according to claim 17 or 18, further comprising heparin, optionally in the presence of antithrombin III, or Atheplex, respectively.

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